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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,766	02/08/2002	Marvin J. Slepian	MJS 104	2905

23579 7590 12/12/2007

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/072,766	Applicant(s) SLEPIAN, MARVIN J.	
	Examiner Maria B. Marvich, PhD	Art Unit 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *13 November 2007*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1, 3, 6, 7, 13,15 -25, 28, 29, 31-33 and 35-37*.
   Claim(s) withdrawn from consideration: *8-12,26,27 and 30*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Maria Marvich/

Continuation of 5. Applicant's reply has overcome the following rejection(s): The objections to claims 18 and 19 have been overcome by amendment as have the rejection of claims 1, 3, 6-7, 13 and 15-24 under 35 USC first paragraph for New Matter.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants reply has not overcome the rejections under 35 USC 102 and 103. Applicants' arguments in the amendment filed 11/13/07 are acknowledged but are not persuasive in overturning the rejections. At issue is whether the insertion of a needle or catheter into the heart tissue will create a void, cavity, containment are or reservoir. Applicants argue that the needle must be of specific bore size to avoid simply displacing tissue versus removing the tissue. Applicants argue that their invention meets the requirements to remove while the prior art simply displaces tissue. However, it is not clear how applicants have been able to distinguish bore size between the two as neither provides adequate details to do so. To the contrary, the instant specification states, "Voids may be created via simple catheter, trochar or needle insertion. The void may be of identical size to the insertion device. Alternatively, the void may be made larger via expansile cutter systems which fan-out in a radial or conical or other geometric shape way." Altman '716 and Altman '887 teach formation of channels in the heart tissue with needles into which drugs are deposited whiel Altman '887 also teaches use of expansile systems which would be expected to increase the channel area. As depicted in figure 8, these two arms spread the tissue apart, which inherently creates a space. Haim teaches use of laser beams to create the channels. Applicants argue that the requirement that the particles be injected and then steps taken to ensure that these particles are retained suggests that the method is distinct from the instant claims in that there is no void into which the particles are deposited. However, these steps do not teach that a channel which is explicity created in Altman '716 and '887 from the needle track is insufficient to act as a void, cavity, containment or reservoir area. The point of the void, cavity, containment or reservoir area is to function as a depot point for diffusion or dispersion of the drug or other agent tht is injected in the istnant invention. SImilarly, Altman and Haim describe conditions for deposting drugs or other agents into a channel which then disperse or diffuse into the surrounding tissues and these agents are injected into the space. A channel is "a long narrow furrow cut either by a natural process (such as erosion) or by a tool (as e.g. a groove in a phonograph record)" and is an unfilled space and into this space the drugs are injected. The compounds are contained in polymeric matrices (i.e. see Altman '716, col 6, line 8-10) for controlled release following implantation in the myocardium. Noen of the three methods are drawn to treatment within the spinal cord.